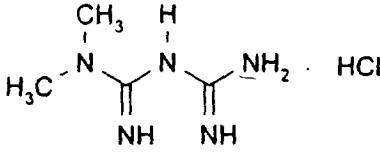


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-357/S019

CHEMISTRY REVIEW(S)

DEC 1 2000

CHEMIST'S REVIEW		
Organization CDER/HFD-510 Division of Metabolism and Endocrine Drug Products		NDA # 20-357 Approved: 29-DEC-1994
Name and Address of Applicant: Bristol-Myers Squibb (BMS) Pharmaceutical Research Institute Princeton, NJ 08543-400 P.O Box 4000 (609) 252-4000 (609) 252-4732		Supplement SE5-019 Doc 15-FEB-2000 Rec. 15-FEB-2000 Name Of The Drug Glucophage Tablets Nonproprietary Name Metformin Hydrochloride Tablets
Supplement provides for pediatric exclusivity for glucophage (metformin hydrochloride) tablets.		New Correspondence --
Pharmacological Category Antihyperglycemic Agent	How Dispensed Oral Rx	Supporting Documents --
Dosage Form Tablets	Potencies 500 — 850 and 1000 mg	
Chemical Name and Structure Metformin Hydrochloride $C_4H_{11}N_5 \cdot HCl$ MW = 129.17 + 36.46 = 165.63 CAS 657-24-9 (base) 1115-70-4 (hydrochloride) <div style="text-align: center;">  </div> <i>N,N</i> -Dimethylbiguanide hydrochloride or <i>N,N</i> -Dimethylimidodicarbonimidic diamide monohydrochloride		
Comments: A request for categorical exclusion is provided on page 20. This action is not expected to increase the use of the active moiety metformin hydrochloride. In addition, to the knowledge of the applicant no extraordinary circumstances exist [21 CFR§25.15(d)]. The subject of the proposed action meets the requirements for a categorical exclusion from submitting an environmental assessment, 21 CFR§25.31(a).		
Conclusions and Recommendations There are no CMC changes in the drug substance nor the drug product. From the chemistry point of view, this supplement can be approved.		
Reviewer Name (and signature) Xavier Ysern, PhD <i>/S/</i>		Date Completed: 14-DEC-2000
R/D Init. <i>/S/</i> <i>for Stephen Moore</i>		filename: /nda/20537s19.doc
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AP